K132799
Page 1 of 5

510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:
October 27, 2013

Submitter's Information: 21 CFR 807.92(a)(1)

NOV 07 2013

Mr. Cody D. Ebberson,
CEO Clariso, Inc.
55 Page Street #824
San Francisco, CA 94102
Email: cody@clariso.com

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	CLARISO PACS™
Common Name:	Picture, archive and communications system
Classification Name:	System, Image Processing, Radiological
Product Code:	LLZ

Predicate Device: 21 CFR 807. 92(a)(3)

Device Classification Name	system, image processing, radiological
510(k) Number	K061421
Device Name	ERAD PACS
Original Applicant	ERAD, INC. 16303 Panoramic Way San Leandro, CA 94578
Regulation Number	892.2050
Classification Product Code	LLZ
Decision Date	07/25/2006
Decision	substantially equivalent (SE)
Classification Advisory Committee	Radiology
Review Advisory Committee	Radiology
summary	summary
Type	Traditional
Reviewed by Third Party	No
Expedited Review	No
Combination Product	No

Device Description: 21 CFR 807 92(a)(4)

CLARISO PACS™ is a software system to be used to view DICOM compliant studies, which are stored within the CLARISO PACS™. CLARISO PACS™ is intended for professional use only as a viewing tool for studies within a medical facility. CLARISO PACS™ is a 'Continuous Use' device. This device is also compliant with HIPAA regulations regarding patient privacy (such as restricting access to particular studies, logging access to data.). Since there is no direct patient interaction with the device, there is no possibility that CLARISO PACS™ might lead to a fatal fault or injury to the patient. The only two most likely causes of a fault would be the change of the computing environment of the Client system, or a mislabeling of the DICOM studies used by the Viewer. In the best-case scenario, CLARISO PACS™ would be able to operate safely in spite of such faults. The strategy of CLARISO PACS™ in fault handling is to keep its normal operation as much as it can. The CLARISO PACS™ is

intended to work as a standalone service that provides common PACS functionality. The main objective of CLARISO PACS™ is to be a service that can be embedded in other applications that require PACS functionality.

CLARISO PACS™ has four main uses:

- Hard copy replacement: PACS replaces hard-copy based means of managing medical images, such as film archives.
- Remote access: It expands on the possibilities of conventional systems by providing capabilities of off-site viewing and reporting (distance education, tele-diagnosis). It enables practitioners in different physical locations to access the same information simultaneously for teleradiology.
- Electronic image integration platform: PACS provides the electronic platform for radiology images interfacing with other medical automation systems such as Hospital Information System (HIS), Electronic Medical Record (EMR), Practice Management Software, and Radiology Information System (RIS).
- Radiology Workflow Management: PACS is used by radiology personnel to manage the workflow of patient exams.

Indications for Use: 21 CFR 807 92(a)(5)

CLARISO PACS™ is a software Teleradiology system used to receive DICOM images, scheduling information and textual reports, organize and store them in an internal format, and to make that information available across a network via web and customized user interfaces. CLARISO PACS™ is used by hospitals, imaging centers, radiologist reading practices. CLARISO PACS™ is not intended for the acquisition of mammographic image data and is meant to be used by qualified medical personnel only who are qualified to create and diagnose radiological image data.

Technological Characteristics: 21 CFR 807 92(a)(6)

CLARISO PACS™ is a software application that handles and manipulates digital medical images. The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed. In general, a PACS (Picture Archiving and Communication System) is a medical imaging technology which provides storage of, and convenient access to, images from multiple modalities. Electronic images and reports are transmitted digitally via PACS; this eliminates the need to manually file, retrieve, or transport film jackets. The universal format for PACS image storage and transfer is DICOM 3.x (Digital Imaging and Communications in Medicine). Non-image data, such as scanned documents, may be incorporated using consumer industry standard formats like PDF (Portable Document Format), once encapsulated in DICOM. The new device and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. The new device does not raise any new potential safety risks and is equivalent in performance to the existing legally marketed devices. Both systems have been developed to replace traditional film handling in radiology. The 2 devices are substantially equivalent in the areas of design, architecture, general function, application, and intended use. The predicate device and the new device are compared below:

Item	Functionality	Predicate device (ERAD PACS)	CLARISO PACS™	If different, Impact on Safety and or Efficacy
1	Web Browser Software	Custom Microsoft Windows application	Google Chrome for all features. Microsoft Internet Explorer & Mozilla Firefox for features except the DICOM Viewer	Provides access in the Google Chrome web browser instead of using a custom Windows application. See reference #1 below.

2	Intended use	Acquiring, viewing, editing and storing radiographs and related patients images	Same	No difference
3	Intended user	Radiologist	Radiologist	No difference
4	Network	10/100/100 Ethernet	Same	No difference
5	Monitor	Above 19inch monitor (Above 1280x900)	Same, Using 1280x1024	No difference
6	User interaction/input	Mouse and keyboard	Same	No difference
7	Import / export images	Yes	Yes	No difference
8	Acquisition devices	CT, MR, US, PET	Same	No difference
9	Image organization	Yes. Patient ID, Name, study instance UID	Same	No difference
10	Image search available	Yes	Yes	No difference
11	Image storage	Yes	Yes	No difference
12	Database software	MySQL	MySQL	No difference
13	Greyscale Image Rendering	Yes	Yes	No difference
14	RGB Image Rendering	Yes	Yes	No difference
15	Localizer Lines	Yes	Yes	No difference
16	Localizer Point	Yes	Yes	No difference
17	Orientation Markers	Yes	Yes	No difference
18	Distance Markers	Yes	Yes	No difference
19	Study Data Overlays	Yes	Yes	No difference
20	Stack Navigation	Yes	Yes	No difference
21	Window Level	Yes	Yes	No difference
22	Zoom in on images	Yes	Yes	No difference
23	Panning	Yes	Yes	No difference
24	Horizontal/Vertical Flip	Yes	Yes	No difference
25	Clockwise/Counterclockwise rotate	Yes	Yes	No difference
26	Invert image	Yes	Yes	No difference
27	Text Annotation	Yes	Yes	No difference
28	Area measurement annotation	Yes	Yes	No difference
29	Angle measurement annotation	Yes	Yes	No difference
30	Cobb Angle Measurement Annotation	Yes	Yes	No difference

31	Image annotation	Yes	Yes	No difference
32	Image operations	Yes	Yes	No difference
33	Security	Yes	Yes	No difference
34	DICOM 3.0 conformance	Yes	Yes	No difference
35	Worklist	Yes	Yes	No difference
36	Thumbnail viewing	Yes	Different sizes of thumbnails available	Provides 3 sizes of thumbnails instead of just one size. See Reference #2 below.
37	Login	Yes	Yes	No difference
38	Audit	Yes	Enriched audit ability	Provides the ability to see the audit trail at any time in real time. See Reference #3 below.

Ref # related to differences	Functionality or Item	Impact on Safety and or Efficacy
1	Software/Hardware Requirements	The new device CLARISO PACS™ requires Google Chrome Browser to view image data. The predicate device, eRAD PACS installs a custom Windows application to view image data. The new device uses the Google Chrome web browser. Increasingly, practitioners prefer to use Google Chrome instead of installing a Windows Application because web browsers are more convenient and users already know how to use them. The function of the hardware and software are the same and the use of a Google Chrome web browser in the subject device does not raise any new potential safety risks. The subject device is equivalent in performance to existing legally marketed devices and was based upon the software developed for the predicate eRAD PACS. Therefore, it is our determination that there is "No impact on safety or efficacy"
36	Thumbnail viewing	There are slight differences in Thumbnail Viewing. The new device CLARISO PACS™ supports three sizes of thumbnails on preview, small, medium and large. The old device only supports medium sized thumbnails. This difference differences does not raise any new potential safety risks and gives the user additional flexibility. The subject device is equivalent in performance to existing legally marketed devices and was based upon the software developed for the predicate eRAD PACS. Therefore, it is our determination that there is "No impact on safety or efficacy"
38	Audit	The new device adds a tool to view access logs in real time. The predicate device eRAD PACS doesn't have this kind of tool. In ERAD PACS audit trails need to be generated offline with a lag. Since the subject device has real time log access it gives the user added flexibility and does not raise any new potential safety risks. The subject device is equivalent in performance to existing legally marketed devices and was based upon the software developed for the predicate eRAD PACS. Therefore, it is our determination that there is "No impact on safety or efficacy"

Nonclinical Testing:

The complete CLARISO PACS™ system configuration has been assessed and tested at the factory and has passed all in-house testing criteria. The Verification & Validation Test Plan was designed to evaluate all input functions, output functions, and actions performed by the CLARISO PACS™ software in each operational mode and followed the process documented in the Validation Test Plan.

K132799
Page 5 of 5

510(k) Summary

Nonclinical testing results are provided in the 510(k). Validation testing indicated that as required by the risk analysis, designated individuals performed all verification and validation activities and that the results demonstrated that the predetermined acceptance criteria were met. If the device is installed by CLARISO Inc., integration and installations verification tests are conducted against acceptance criteria prior to release to the client.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for CLARISO PACS™ contains adequate information, data, and nonclinical test results to enable FDA - CDRH to determine substantial equivalence to the predicate device.

The subject device will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The subject and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. The modification to the subject device does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices.

Nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the predicate device.

Therefore, CLARISO PACS™ is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 7, 2013

Clariso, Inc.
% Mr. Carl Alletto
Consultant
OTech, Inc.
111 Melanie Drive
AUBREY TX 76227

Re: K132799
Trade/Device Name: CLARISO PACS™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 28, 2013
Received: November 1, 2013

Dear Mr. Alletto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

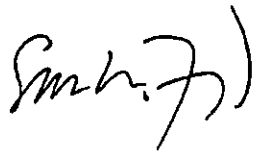
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132799

Device Name: CLARISO PACS

Indications for Use:

CLARISO PACS is a software Teleradiology system used to receive DICOM images, scheduling information and textual reports, organize and store them in an internal format, and to make that information available across a network via web and customized user interfaces. CLARISO PACS is used by hospitals, imaging centers, radiologist reading practices.

CLARISO PACS is not intended for the acquisition of mammographic image data and is meant to be used by qualified medical personnel only who are qualified to create and diagnose radiological image data.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K132799